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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/485,583 | 02/14/2000 | KOICHI ENDO | ENDO=12 | 5957 |

7590 04/09/2003

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[REDACTED] EXAMINER

YU, GINA C

[REDACTED] ART UNIT PAPER NUMBER

1617

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/485,583 | ENDO ET AL. |
| | Examiner | Art Unit |
| | Gina C. Yu | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 January 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 19-21 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-11, 15-18 and 22-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>19</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2003 has been entered. Claims 8-25 are pending, of which claims 12-14 and 19-21 have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "kit" renders the claims vague and indefinite, as it is not clear as to what type or form of kit applicants are claiming. The term is not defined in the applicants' disclosure, nor it is readily apparent to a one having ordinary skill in the art.

The term "instruction" also renders the claims vague and indefinite, as there is no explanation as to how the "kit" is to be used.

Claim Rejections - 35 USC § 103

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 8-11, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Pharmacological Basis of Therapeutics (1996) ("Therapeutics") in view of Hukkanen et al. (Endocrinology) and Moore et al. (J. of Med.).

Therapeutics teaches the method of treating osteoporosis by administering estrogen, thereby inhibiting the activity of IL-6 (p. 1541, col. 1, last paragraph).

The reference fails to teach a kit comprising L-N-6-(1-iminoethyl)lysine, the elected species, nor does it teach a method of using the same to treat osteoporosis.

Hukkanen et al. teach that iNOS inhibitors completely inhibit the activity of cytokines such as IL-6. See p. 5452, col. 1, bottom of 1st full paragraph.

Moore et al. teach that L-N-6(1-iminoethyl)lysine is a potent and selective iNOS inhibitor. See p. 3886, abstract. While Moore et al. does not disclose whether the elected iNOS inhibitor, L-N-6-(1-iminoethyl)lysine, meets the recited requirement in instant claims, examiner takes the position that the limitation is an inherent property in the inhibitor itself.

Given the general teachings of Therapeutics that osteoporosis can be treated by inhibiting the activity of IL-6, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the prior arts such as Hukkanen for specific IL-6 inhibitors such as iNOS inhibitors. The skilled artisan would have been further motivated to use L-N-6(1-iminoethyl)lysine, as motivated by Moore et al.,

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because of the expectation that administering the potent and selective iNOS would successfully treat osteoporosis.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
April 7, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

4/7/03